DETAILED ACTION

Introduction

1. Applicants' amendments and remarks filed on 8/11/2008 have been entered. Claim 1 has been amended. Claims 7-24, 26 and 27 are active.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. In response to the amendments, the grounds of rejection have been updated as set forth below. Rejections not maintained are withdrawn.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 3/27/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

5. Applicant argues at Remarks page 7 that

> "The Office Action asserts that the Applicants' election of viscous component as a copolymer of poly(dl-lactic acid) and poly(ethylene glycol) is incommensurate with the specification. Applicants respectfully disagree, and direct the Examiner's attention to the broad disclosure in paragraphs 18 and 20 of the instant application. However, Applicants note with appreciation that the issue is moot in view of the Examiner's consideration of copolymers of dl-lactic acid, which would include a copolymer of poly(dl-lactic acid) and poly(ethylene glycol)."

It is noted that the original specification does not have numbered paragraphs, "paragraphs 18 and 20" are taken as [0018] and [0020] in the US Pat. Appl. No. 2007/0065652. After a careful review of the specification, the examiner maintains that applicant's election of viscous component as "a copolymer of poly(dl-lactic acid) and poly(ethylene glycol)" is incommensurate with the specification, because the elected species "a copolymer of poly(dl-lactic acid) and poly(ethylene glycol)" is absent from the list of viscous components in [0020]. For the present Office action, the elected viscous component is again interpreted as a copolymer of dl-lactic acid.

Rejections Based on Prior Art

6. Claims 7-24, 26 and 27 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dalal et al. [US 2003/0180376].

Dalal's invention relates to a bone replacement material. The material comprises porous ß-tricalcium phosphate, biodegradable agents (inclusions) and binders [abstract; 0006]. The biodegradable agents selected from the group consisting of polyorthoesters, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(p-dioxanone), and co-polymers thereof [0073]. The binders are flowable at room temperature and are solubilized in warm or hot aqueous solutions and cross-linked [0089-0090]. Total porosity is in the range of 5-80% [0062]. The proportion of pore-forming agent is preferably 10-50 w% [0080].

For claims 7-12, 14, 15 and 27, Dalal teaches all the features of the claimed invention. Dalal is silent about the newly added limitation "wherein the inclusions provide an interconnected fibrous network within the bone replacement material". However, the term

"fibrous network" is interpreted as meaning "uniformly distributed throughout" [see specification page 7, bottom paragraph; Fig. 3]. Since the binders of Dalal is flowable at room temperature and are solubilized in warm or hot aqueous solutions, and Dalal further teaches that the bone replacement material contains uniformly distributed pores [0059], which infers that all the components, including the biodegradable agents, of the bone replacement are uniformly distributed throughout, the newly added limitation is deemed to be either anticipated by Dalal, or obviously provided by practicing the invention of prior art.

For claims 13, 17 and 19-21, since Dalal's teaching encompasses the same biodegradable polymer being used as viscous component and inclusions, the shapes of the inclusion is indistinguishable from the viscous component, i.e., portions of a single biodegradable polymer inherently read on the two claimed components, including various embedded shapes and sizes of the inclusions.

For claims 16 and 22, since the process limitations have not been shown on the record to produce a patentably distinct article, the formed articles are rendered *prima facie* obvious, and this limitations at the present time has not been given patentable weight.

For claim 18, within typical densities of component materials, the amount of volume percent of the inclusion is either anticipated by a single biodegradable (pore forming) agent of 10-50 w%, or obviously provided by practicing the invention of prior art, dictated by the same end use.

For claim 26, since Dalal teaches the same end use of the claimed invention, a workable compressive strength is deemed to be either anticipated, or an obvious routine optimization, dictated by the same property requirements of end use.

Conclusion

7. Pointing to newly added limitation, and Dalal's teaching that each pore is a single separate void partitioned by walls and is not interconnected, applicant argues at Remarks page 8 that

> "Applicants submit that the cited reference does not disclose each and every element set forth in the pending claims."

However, Since the binders of Dalal is flowable at room temperature and are solubilized in warm or hot aqueous solutions, and Dalal further teaches that the bone replacement material contains uniformly distributed pores [0059], which infers that all the components, including the biodegradable agents, of the bone replacement are uniformly distributed throughout, the newly added limitation is deemed to be either anticipated by Dalal, or obviously provided by practicing the invention of prior art. More particularly, since the "biodegradable agents" and "pores" are not the same components in the bone replacement material, it is unseen how the claim language of instant invention would exclude the discrete pore structure of Dalal, applicant's argument is not understood.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTOR S. CHANG whose telephone number is (571)272-1474. The examiner can normally be reached on 7:00 am - 5:00 pm, Tuesday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor S Chang/
Primary Examiner, Art Unit 1794